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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/365,065 07/30/99 COLLINS

D 10847/002001

EXAMINER

HM12/0208

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ART UNIT

PAPER NUMBER

13

1645
DATE MAILED:

02/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory ActionApplication No.
09/365,065

Applicant(s)

Collins

Examiner

Robert A. Zeman

Group Art Unit

1645

THE PERIOD FOR RESPONSE: [check only a) or b)]

- a) ☐ expires _____ months from the mailing date of the final rejection.
- b) ☒ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

- ☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on _____ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on Dec 14, 2000 has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:

- ☒ The proposed amendment(s):

☒ will be entered upon filing of a Notice of Appeal and an Appeal Brief.

☐ will not be entered because:

- ☐ they raise new issues that would require further consideration and/or search. (See note below).
- ☐ they raise the issue of new matter. (See note below).
- ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
- ☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE:

- ☐ Applicant's response has overcome the following rejection(s):

- ☐ Newly proposed or amended claims _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.
- ☐ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because:

- ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

- ☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: _____

Claims objected to: _____

Claims rejected: 1-21

- ☐ The proposed drawing correction filed on _____ ☐ has ☐ has not been approved by the Examiner.
- ☐ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ .
- ☐ Other

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DETAILED ACTION

Response to Amendment

The after final amendment filed December 14, 2000 in response to the final rejection outlined in Paper No. 10 is acknowledged and the amendment entered. Said amendment and response has been considered but is not deemed to place the application in condition for allowance. Claims 1 and 20 have been amended. Claims 1-21 are still pending.

Objections to the Specification Withdrawn

The objection to the specification for the use of the trademarks Texas RedTM, Oregon GreenTM, CascadeTM, Nonidet P40 and Triton-X 100 is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The rejection of claims 1-21 under 35 U.S.C. 103(a) as being unpatentable over Kortright et al. (U.S. Patent 4,870,003) in view of Jackson et al. (U.S. Patent 5,776,709) is maintained essentially for reasons of record.

Applicant argues that claim 1 relates to a method for simultaneously measuring both members of a binding pair in a biological sample and that said method includes: providing a solid phase reagent comprising a particle coated with capture antibodies having specific affinities for member A of the binding pair; contacting a biological sample with said solid phase reagent to form the first reacted particle; contacting the first reacted particle with first antibodies having specific binding affinities for member A and labeled with a given label, and with second antibodies having specific binding affinities for member B and labeled with a second label forming the second reacted particle, and measuring the labels on the second reacted particle using flow cytometry. Applicant further argues that while Kortright et al. discloses a system for detecting HIV antigen and anti-HIV antibody they do not teach or suggest that two antibodies, one having specificity for member A and one having specificity for member B, that are differently labeled that can be used to simultaneously measure both members of a binding pair. Applicant argues Kortright et al. merely disclose a system to determine if there is "free" antigen or "free" antibody in a sample and there for is incapable of detecting an immune complex of virus and antibody. Applicant further argues that while Jackson et al. disclose flow cytometry methods for analyzing populations of leukocytes using two or more fluorescent labels they do not teach or suggest a method or a kit for the simultaneous measurement of both members of a binding pair. Applicant concludes that

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Jackson et al. does not remedy the deficiencies of the disclosure of Kortright et al. since it does not teach or suggest that both members of a binding pair can be measured simultaneously.

Applicants arguments have been fully considered and have been deemed not persuasive.

Kortright et al. disclose a solid-phase immunoassay for the simultaneous detection of both members of a binding pair in physiological fluid through the utilization of labeled antibodies with specific binding affinities said binding pair members. Kortright et al. further disclose methods consisting of coating a solid phase reagent with a capture antibody (anti-HIV monoclonal antibody); exposing said solid phase reagent to a biological sample to bind one member of the binding pair; and adding labeled antibodies to detect the levels of each member of the binding pair (see column 4, lines 1-32). Kortright et al, however, disclose the use of enzyme labels for measuring binding pair levels and the level of the second binding pair member is determined indirectly as an increase over the "spiked" positive control. Jackson et al. disclose not only the use of fluorescently labeled antibodies but also the methods for using multiple stains simultaneously in flow cytometry (see example 1 in columns 12 and 13 for an example) which allows for the direct measurement of the level of each binding pair member. Jackson et al also disclose the benefit of using multiple fluorescent labels as opposed to other labeling techniques (such as enzyme labels). Multiple fluorescent labels "provide(s) a means for obtaining a maximum amount of information with the minimal sample manipulation, resulting in time savings both in sample preparation and instrument data acquisition" The method allows detection of two or more subpopulations depending on the number of fluorochrome-labels used. Therefore, it would have been obvious to

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one of skill in the art to use the fluorochrome labeling disclosed by Jackson et al. in the methods disclosed by Kortright et al. in order to reap the benefits of direct measurement (both qualitative and quantitative) of each label (and hence each binding pair member) as well as the reduction in sample preparation and data acquisition. One would have a reasonable expectation of success since Kortright et al. suggest the use of other labeling systems, specifically “fluorescers” (see column 7 lines 29-32). Additionally, the methods disclosed by Kortright et al. can be applied to a myriad of binding pairs including: various viruses and antibodies; enzymes and its ligands or substrates; cytokines and their receptors; and vitamins and their receptors to name a few.

Applicant is reminded that the aforementioned rejection is based on the **combination** of the cited references.

Conclusion

No claim is allowed.

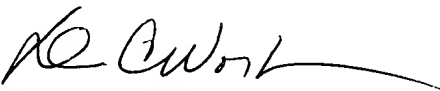
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

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If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Lynette Smith, can be reached at (703)308-3909.



DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman

February 6, 2001